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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A.,	:	Civil Action No. 3:10-CV-01723-JAP-TJB
Plaintiffs and Counterclaim-Defendants,	:	
v.	:	
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED,	:	REPLY BRIEF IN SUPPORT OF TAKEDA'S MOTION FOR SPOILIATION SANCTIONS IN THE FORM OF EXCLUSION OF ZYDUS' EVIDENCE OF PARTICLE SIZE TESTING ON PRE-TABLETED GRANULES
Defendants and Counterclaim-Plaintiffs.	:	CONFIDENTIAL – TO BE FILED UNDER SEAL

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The Takeda Plaintiffs¹ ("Takeda") submit this reply brief in support of their motion for spoliation sanctions against Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Zydus").

PRELIMINARY STATEMENT

Zydus argues there has been no spoliation because [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] Zydus' argument boils down to "I fed my homework to the dog, and I didn't know I had to turn my homework in anyway."

First, spoliation is not limited to destruction of evidence. Spoliation includes *failure to preserve* evidence. [REDACTED]

[REDACTED] Second, Paragraph IV certifications trigger subsequent Hatch-Waxman patent litigation, and Zydus knows this well. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

¹ The Takeda Plaintiffs are Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc.

[REDACTED]

[REDACTED]

[REDACTED]

² See Takeda's Opposition to Zydus' Motion for Leave to Amend Its Invalidity and Non-Infringement Contentions, D.I. 148, [REDACTED]

[REDACTED]

[REDACTED] Takeda's motion for spoliation sanctions should be granted.

ARGUMENT

A. [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED] But "[s]poliation is 'the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation.'" *Mosaid Techs. Inc. v. Samsung Elecs. Co., Ltd.*, 348 F. Supp. 2d 332, 335 (D.N.J. 2004) (citation omitted) (emphasis added). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Zydus has spoliated evidence, and that spoliation warrants granting Takeda's motion.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

³ Takeda notes that granting this motion does not prevent Zydus from maintaining its non-infringement case against the Takeda patents. Takeda, of course, bears the burden of proof of infringement. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

B.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁴ This Court's recent decision in *Schering Corp. v. Apotex Inc.*, No. 09-6373 (PGS) (D.N.J. Mar. 7, 2012) (Bongiovanni, J.), attached as Ex. 1, is not to the contrary. In that case, this Court denied plaintiff's spoliation motion because plaintiff inexplicably delayed four months in raising the issue until one month before trial. *Id.* at 1-2. Here, by contrast, Takeda filed its motion promptly, [REDACTED]

[REDACTED] because "time certainly is of the essence" in "cases such as this," sanctions here are warranted to preserve the case schedule. *Id.* at 2. Takeda is bringing this motion to ensure that the 30 month stay is not endangered.

[illegible]

⁵ See Notice Letter (Feb. 19, 2010) at 62, attached as Ex. 2; Defendants' Non-infringement and Invalidity Contentions (Aug. 16, 2010) (Ex. 3); Defendants' Amended Non-infringement and Invalidity Contentions (Dec. 3, 2010) (Ex. 4).

[REDACTED]

C. [REDACTED]

[REDACTED]

First, Paragraph IV certifications and patent litigation go hand-in-hand; there is a well-established, statutorily-mandated cause-and-effect between a Paragraph IV certification and a subsequent suit for patent infringement.⁷ [REDACTED]

⁶ [REDACTED]

[REDACTED] See Ex. 5 (2/17/12 S. Moore email to A. Chow) [REDACTED]

[REDACTED] See Ex. 6 (3/6/12 S. Moore email to A. Chow). [REDACTED]

⁷ See, e.g., *Eisai Co. v. Teva Pharms. USA, Inc.*, 247 F.R.D. 440, 442 (D.N.J. 2007) ("Thus, when Teva sent its Notice Letter, it must have anticipated that Eisai would file suit before the statutory deadline. Given the cause-and-effect between a Paragraph IV Certification and a subsequent suit for infringement, this Court finds that the retention of an expert with an eye towards filing such a Certification is done in anticipation of litigation."); *In re Gabapentin*

[REDACTED]
[REDACTED]
[REDACTED] A Westlaw search indicates that Zydus has been involved in well over a dozen ANDA litigations; it is well-acquainted with the litigation-related implications of a Paragraph IV certification.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (See Ex. 7, Zydus' Privilege Logs at Privilege Nos. 367, 498, 527, 540, 541, 585). [REDACTED]

[REDACTED] See *id.* at Privilege Nos. 299, 301, 565, 567, 569). [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Patent Litig., 214 F.R.D. 178, 185 (D.N.J. 2003) ("Simply stated, litigation (in the form of a patent infringement action) is almost certain to follow a Paragraph IV Certification.")

⁸ See *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*, Civil Action No. 07-CV-5855 (DMC-JAD), 2010 WL 2652412, at *3, 5 (D.N.J. July 1, 2010) (observing that "[o]nce a party reasonably anticipates litigation, it must suspend its routine document retention/destruction policy and put in place a 'litigation hold' to ensure the preservation of relevant documents' and concluding that defendants' 'duty to impose a litigation hold and to institute legal monitoring for purposes of compliance arose no later than February 23, 2006,' when defendants first asserted work product immunity) (citation omitted); *Medeva Pharma Suisse A.G. v. Roxane Labs., Inc.*, Civil Action No. 07-5165 (FLW), 2011 WL 310697, at *15 (D.N.J. Jan. 28, 2011) (Bongiovanni, J.) ("[T]he court cannot fathom why Roxane failed to institute a litigation hold . . . perhaps as far back as July 31, 2001 if its privilege log claiming work product protection over a document with that date is to be credited . . .").

[REDACTED]

[REDACTED]

[REDACTED]

Moreover, the Takeda and Ethypharm Orange Book-listed patents are formulation patents; infringement or non-infringement is highly dependent on the specific formulation at issue. The fact that Teva may have designed around the Takeda and Ethypharm patents with its ODT formulation has no bearing whatsoever on whether or not Zydus' separate and distinct ODT formulation infringes. In fact, Takeda did not assert the Takeda patents against Teva at the claim construction, expert and trial phases of the case. In sharp contrast, Takeda has asserted the Takeda patents against Zydus at the claim construction and expert phases thus far; Takeda anticipates asserting those patents at trial as well.

D. The Court Can Rely on Its Inherent Authority to Issue Sanctions

Zydus argues, at length, that sanctions are somehow barred because Takeda did not previously move to compel [REDACTED] See Opp. Br. at p. 14-17 (citing to Fed. R. Civ. P. 37). Zydus is wrong. A court order does not bring back that which has already been destroyed. A motion to compel is hardly requisite for sanctions here; the Court can impose spoliation sanctions pursuant to its inherent authority as well as the Federal Rules of Civil Procedure. See *Mosaid Techs. Inc. v. Samsung Elecs. Co.*, 348 F. Supp. 2d 332, 335 (D.N.J. 2004) ("This Court has the authority to impose spoliation sanctions pursuant to the Federal Rules of Civil Procedure and this Court's inherent authority."); *Medeva Pharma Suisse A.G. v. Roxane Labs., Inc.*, Civil Action No. 07-5165 (FLW), 2011 WL 310697, at *14 (D.N.J. Jan. 28, 2011) (Bongiovanni, J.) ("The Court has authority to impose spoliation sanctions pursuant to both the Federal Rules of Civil Procedure and its inherent authority, and the choice of which sanction should be imposed rests in the sound discretion of the Court.").

Takeda was under no obligation to move to compete

CONCLUSION

Because Zydus has unquestionably failed to preserve evidence when it knew that litigation was reasonably foreseeable, it should not be able to benefit from that evidence. [REDACTED]

[REDACTED] Zydus' spoliation severely prejudices Takeda and warrants sanctions. Accordingly, Takeda respectfully requests that this Court exclude Zydus' evidence of particle size testing of pre-tableted granules [REDACTED]

Dated: March 12, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing REPLY BRIEF IN SUPPORT OF TAKEDA'S MOTION FOR SPOILIATION SANCTIONS IN THE FORM OF EXCLUSION OF ZYDUS' EVIDENCE OF PARTICLE SIZE TESTING ON PRE-TABLETED GRANULES and supporting documents were caused to be served on March 12, 2012 via email and/or the ECF system upon all counsel of record.

By: s/John E. Flaherty
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